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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,157

07/27/2007

Akihiko Kameyama

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12/23/2008

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EXAMINER

XU, XIAOYUN

ART UNIT

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1797

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,157	<b>Applicant(s)</b> KAMEYAMA ET AL.	
	<b>Examiner</b> ROBERT XU	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/18/2006</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The data processing part of the method is not clearly and specifically defined in Claim 13.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 1-7, 10 and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Takegawa et al. (Rapid Communication in Mass Spectrometry, 2004, IDS) (Takegawa).

In regard to Claims 1 and 3, Takegawa teaches a method of identifying an analysis-objective sugar chain structure using a mass spectrometry by comparing a measured MS3 fragment pattern with a reference MS3 fragment pattern stored in a database, where the measured MS3 fragment pattern is a fragmentation pattern of MS2 fragment ion included in a measured MS2 fragment pattern obtained by subjecting the sugar chain to a fragmentation mass spectrometry (see abstract).

Takegawa teaches selecting MS2 fragment ions for MS3 fragmentation (see page 388, right col. 2<sup>nd</sup> paragraph, Figure 5). Takegawa also teaches that when the mutual similarity (correlation coefficient) among the MS2 fragment patterns are small, the isomers of the sugar can be differentiated by using the fragment ion intensities of MS2 spectra (see page 387, right col. 1<sup>st</sup> paragraph, and page 388, right col. 1<sup>st</sup> paragraph). Takegawa does not specifically teach selecting MS3 precursor based on least similarity (correlation coefficient) among MS3 fragment patterns. However, Takegawa teaches the idea that when precursor has small similarity (correlation coefficient) among the fragment patterns, the isomers of the sugar can be differentiated by the fragmentation pattern (see page 388, right col. 1<sup>st</sup> paragraph). Takegawa applied this idea on determining whether the MS2 fragment patterns will differentiating the isoforms. It would have been obvious for one of ordinary skill in the art to apply the same idea on selecting the precursor of MS3 fragment patterns, because this is will facilitate the quick identification of the isoforms. Takegawa also teaches developing a reliable MS<sub>n</sub> database designed for oligosaccharide structural assignment (see page 390, left col.).

In regard to Claims 2 and 4, Takegawa does not specifically teach using MS<sub>4</sub> or MS<sub>n</sub> fragment patterns to identify a sugar chain. However, Takegawa teaches developing a reliable MS<sub>n</sub> database designed for oligosaccharide structural assignment (see page 390, left col.). From MS<sub>3</sub> to MS<sub>4</sub> or MS<sub>n</sub> and selecting the precursor for MS<sub>4</sub> or MS<sub>n</sub> is a natural extension of the technology, because it simply repeats the same process of from MS<sub>2</sub> to MS<sub>3</sub> by choosing a MS<sub>3</sub> fragment as the precursor of MS<sub>4</sub> and measure the fragment pattern of MS<sub>4</sub>. It would have been obvious for one of ordinary skill in the art to use the idea of using the fragment patterns of least mutual similarity (correlation coefficient) to differentiate the isoforms as taught by Takegawa in Takegawa's method to further extend the fragment pattern from MS<sub>3</sub> to MS<sub>4</sub> or MS<sub>n</sub> with reasonable expectation that this would provide more information for recognizing the isoforms of the sugar chain.

In regard to Claim 5, storing reference MS<sub>n+1</sub> fragment patterns in the database by associating with a mass to charge ratio of the precursor ion is known in the art and also taught by Takegawa (see page 390).

In regard to Claim 6, Takegawa teaches selecting MS<sub>n</sub> with strong peak ( $m/z$  790) as the precursor of MS<sub>n+1</sub> fragment pattern (see page 387).

In regard to Claim 7, Takegawa teaches that a theoretical composition of sugar chain can be calculated from a measured MS<sub>n</sub> fragment pattern and MS<sub>n+1</sub> fragment patterns stored in the database can be used to further differentiate the isoforms (see page 390). Based on the teaching of Takegawa, it would have been obvious to ordinary skill in the art that the patterns to be compared are restricted in advance.

In regard to Claim 10, calculating Euclidean distance between two vectors as the measure of difference of the two vectors is known in the art. Takegawa teaches calculating correlation coefficient of the two fragment patterns in a similar way (see page 387, right col. 1<sup>st</sup> paragraph). At the time of the invention, it would have been obvious to one of ordinary skill in the art to calculate the dissimilarity of the fragment patterns from the Euclidean distance of the vectors.

In regard to Claim 11, reversing the order of fragment patterns and performing the same Euclidean distance calculation is still a routine calculation of mutual dissimilarity.

6. **Claims 8, 9, 12 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Takegawa in view of Armentrout (Topics of Current Chemistry, 2003).

In regard to Claims 8 and 9, Takegawa does not specifically teach setting a specific fragmentation energy for the fragmentation mass spectroscopy. The fragmentation energy of the fragmentation mass spectroscopy is the energy used for breaking the molecule into fragment. It should be higher or equal to threshold collision-induced dissociation energy which is the minimum energy required to break the molecule. Armentrout teaches how to determine the threshold collision-induced dissociation energy (see abstract). At the time of the invention it would have been obvious to one of ordinary skill in the art to store threshold collision-induced dissociation energy of the precursor in the database and set the fragmentation energy higher than the threshold collision-induced dissociation energy of the precursor in the database so

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that the precursor will be fragmented, because having a higher energy of fragmentation is a necessary requirements for fragmenting molecules in mass spectrometry.

In regard to Claim 12, Takegawa teaches a mass spectrometer for analyzing a sugar chain, which comprises:

a mass spectroscopy part equipped with a means for holding and fragmenting an ion (see page 386),

a database part in which MS<sub>n</sub> fragment patterns of known sugar chains are stored (see page 390), and

a data processing part for controlling the mass spectrometer (see abstract)

In regard to Claim 13, Takegawa teaches a program for carrying out the method (see abstract).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT XU whose telephone number is (571)270-5560. The examiner can normally be reached on Mon-Thur 7:30am-5:00pm, Fri 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

12/19/2008

/Yelena G. Gakh/  
Primary Examiner, Art Unit 1797

RX